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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/671,979	09/26/2003	Jeffrey D. Brady	44805-0001 DI2	8856

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EXAMINER	
HAQ, SHAFIQUL	
ART UNIT	**PAPER NUMBER**
1641	

DATE MAILED: 05/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/671,979	BRADY ET AL.	
	Examiner	Art Unit	
	Shafiqul Haq	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-3 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-3 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 9/26/03.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. NPL and other documents cited in sheet 2 of 2 in IDS have not been considered because copies of those documents were not provided. In order to be in compliance with MPEP 609, III, A (2), applicants must provide copies of all of the references cited in the IDS. These references will become part of the official file of this application. Upon receipt of the missing documents, they will be considered by the examiner when preparing the next office action and a signed copy of form PTO-1449 will be provided with the next office action.
2. Although specific claims are cited and discussed in the rejection below, these rejections are also applicable to all other claims in which the noted problems/language occur.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for preparation (purification) of pyrrole containing compounds, does not reasonably provide enablement for any antigens. The specification does not enable any person skilled in the art to which it pertains, or with which it is most

nearly connected, to make and use the invention commensurate in scope with these claims.

The term "antigen" is a broad term and reads on any substance that elicit immune response and may encompass toxins, foreign blood cells, cells of transplanted organs, bacteria and viruses beside other substances that stimulates immune system.

The specification provides guidance and working examples for preparation (purification) of pyrrole containing biological material from collagen extract, but there in no enablement in the specification for preparation (purification) of other antigens such as bacteria or viruses.

5. Claims 1 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for attachment of biotin labeled derivatizing agent to solid support, does not reasonably provide enablement for attachment of derivatizing agent labeled with other labels such as fluorescein or enzyme. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The "labeled derivatizing agent" in claim 1 encompasses derivatizing agents labeled with various label such as avidin/biotin, enzyme, fluorescein, cyanine etc. (see specification, page 7, lines 1-3).

The specification provides guidance and working examples biotin labeled derivatizing agent for attachment to solid support (see specification, page 23), but

there in no enablement in the specification for attachement of other labeled derivatizing agent to solid support.

6. Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Specification provides working example for elution of pyrrole containing biological compound captured to biotinylated derivatizing agent (specification, page 41, lines 4-30; page 23, compound 10 and claim 3) bound to solid support through a noncovalent interaction. However, there is no written description in the specification how pyrrole containing biological compounds could be eluted from solid support when they are captured to derivatizing agent bound to solid support through a covalent bond (Specification, page 23, compound 9 and claim 2). It is noted that Ehrlich's reagent also forms covalent bond with pyrrole moieties of biological compound (see specification, scheme A).

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

   The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1-3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9. The term "preparing an antigen" in claim 1 of line 1 is confusing. It is not clear whether the term is intended to mean "purification of an antigen" (see specification page 9, lines 19-20) or "making an antigen" (e.g. synthetic antigen).
10. The phrase "optionally labelled derivatizing agent" in claim 1 is not a positive recitaiton and thus it is unclear whether the labelled derivatizing agent is a required component of the claimed invention. It is also unclear what is encompassed by the term "derivatizing agent" (i.e the nature/structure of the derivatizing agent).
11. The term "able to" in claim 1 is not a positive recitation and thus is indefinite.
12. Claim 1 is indefinite because it is not clear what is encompassed by the term "detectable molecule" in line 9.
13. With respect to paragraphs a) and b) of claim 1, it is not clear what's the utility of the labeled derivatizing agent in the preparation/purification process when binding agent specific to biological compound (e.g. monoclonal antibody against specific compound) are employed. When binding agent specific to pyrrole containing biological compound (e.g. monoclonal antibody) attached to solid support are used, binding to derivatizing agent will not be a required factor for preparation/purification as the binding agent can itself specifically capture pyrrole containing biological compound without prior binding to derivatizing agent. Therefore, the process of the preparation/purification is confusing and needs to be clarified.
14. With respect to claims 2 and 3, the terms "R^2 is an alkyl group", "R^4 is a heteroalkyl group" are inconsistent with non-terminal nature of the groups "R^2" and "R^4".

15. In claim 2 it is unclear what the chemical nature and scope of the term "linking group" which defines the variable "A" is meant to include.

16. The term "solid support" in Claims 1-3 is unclear and therefore indefinite as this is a relative term and may include numerous solid support such as polystyrene, polyethylene, sephades, sepharose, silica gel, glass etc. Therefore, the undefined "solid support" renders the claims obscure in scope.

17. With respect to claims 2-3, it is unclear what is encompassed by the terms "first partner" and "second partner" as the term may include various binding partners such as antigen-antibody, receptor-ligand, avidin-biotin etc. Therefore, the undefined "first partner" and "second partner" render the claims obscure in scope.

Conclusion

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shafiqul Haq whose telephone number is 571-272-6103. The examiner can normally be reached on 7:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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